JUN - 6 2008 KOS1065

510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

Submitter's Name: Toshiba America Medical Systems, Inc.

Address: PO Box 2068, 2441 Michelle Drive Tustin, CA 92781-2068

Contact: Paul Biggins, Director Regulatory Affairs

**Telephone No.:** (714) 730-5000

**Device Proprietary Name:** SSA-790A, Aplio XG Version 2.2 Common Name: Diagnostic Ultrasound System

Classification:

Regulatory Class: II
Review Category: Tier II

Ultrasonic Pulsed Doppler Imaging System - Product Code: 90-IYN

[Fed. Reg. No.: 892.1550]

Ultrasonic Pulsed Echo Imaging System - Product Code: 90-IYO

[Fed. Reg. No.: 892.1560]

Diagnostic Ultrasonic Transducer – Product Code: 90-ITX

[Fed. Reg. No.: 892.1570]

#### **Identification of Predicate Devices:**

Toshiba America Medical Systems believes that this device is substantially equivalent to:

1. Toshiba SSA-790A, Aplio XG Version 2.00 Diagnostic Ultrasound; 510(k) K072000

2. General Electric Co. VOLUSON E8 Ultrasound System; 510(k) K061682

#### **Device Description:**

The Aplio XG Ultrasound System is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

#### Intended Use:

The Aplio XG is intended to be used for the following type of studies: fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular and musculo-skeletal (both conventional and superficial).

#### **Safety Considerations:**

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-2 (applicable portion), IEC60601-2-37 (applicable portions), and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

#### '.JUN - 6 2008

Toshiba America Medical Systems, Inc. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25<sup>th</sup> Street NW BUFFALO MN 55313

Re: K081065

Trade/Device Name: Aplio XG SSA-790A (v2.2)

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: May 19, 2008 Received: May 21, 2008

#### Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aplio XG SSA-790A (v2.2), as described in your premarket notification:

#### Transducer Model Number

PVT-375BT PVT-661VT PLT-1202S PC-20M PET-510MB PST-25BT

PLT-604AT PLT-704AT PLT-805AT PLT-1204AT **PLT-1204AX** PVT-382BT PVT-674BT PVT-575MV PVT-770RT PST-30BT PST-50AT PST-65AT PLT-704SBT PLT-1204MV PVT-382MV PVT-681MV PET-511BTM PC-50M

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

A Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

System X Transducer Model Aplio XG SSA-790A (v2.2) 510(k) Number(s)

	<u> </u>		T 1	<del></del>	<del></del>	Mode	of O	perat	on			
Clinical Application	В	THI	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic			<u>L.</u>									
Fetal	P	P	P	P	P	P		P	_			P
Abdominal	P	P	P	P	P	P	P	P	P			P
Intraoperative (Specify)	P	P	P	P	P			P				P
Intraoperative Neurological												
Pediatric	P	P	P	P	P	P	P	P	P			P
Small Organ (Specify)*	P	P	P	P	P		-	P	<del>                                     </del>			P P
Neonatal Cephalic	P	P	P	P	P	P	P	P	P			P
Adult Cephalic	P	P	P	P	P	P	-	P	P			P
Cardiac	P	P	P	P	P	P	P	P	P	P		
Transesophageal	P	P	P	P			P	P	P			P
Transrectal	P	P	P	P	P	P	<del>-</del>	P				P
Transvaginal	P	P	P	P	P	P		P	<del> </del>		<del> </del>	P
Transurethral	i		1 1			-	-		<del> </del> _		<del>,</del> -	P
Intravascular			╁┈┧									
Peripheral Vascular	P	P	P	P	P	P		P	P			
Laparoscopic						<u>.</u>	<del> </del>	-		<b> </b>		P
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P
Musculo-skeletal Conventional	P	P	P	P	P	P		P				P

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF
All indications were previously reported via k072000
*: For example: thyroid, parathyroid, breast, scrotum and penis

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

A-4

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

Model <u>PVT-3</u> 510(k) Number(s	375 <u>1</u>				_							
						N. 4 1 -	- (0		· .		· · · · · · · · · · · · · · · · · · ·	·
Clinical Application	В	THI	М	Color Doppler	Power	Mode Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic	Combined (Specify)
Ophthalmic											Flow	
Fetal	P	P	P	P	P	Р		P	-	<u> </u>		P
Abdominal	P	P	P	P	P	P		P				P
Intraoperative (Specify)	<del>                                     </del>				<del> </del>		<del> </del>					. •
Intraoperative Neurological												<u> </u>
Pediatric	P	P	P	P	P	P		P				P
Small Organ (Specify)*								<del> </del>				
Neonatal Cephalic	1 -						·	<del> </del>	<del>                                     </del>			
Adult Cephalic	ļ	<b>—</b>	1				·			<u> </u>		
Cardiac	1	ļ · · · · · -			<u> </u>		1	<del> </del>	<del> </del>	<del> </del>		
Transesophageal		<u> </u>			<b>-</b>			<del>                                     </del>		<del> </del>		
Transrectal	1	<del> </del>	$\dagger$		<del> </del>				<del>                                     </del>		<del> </del>	
Transvaginal	+	<del>                                     </del>	┪	,			-					-
Transurethral	<del> </del>				<u> </u>	<u> </u>	<del></del>		<del>                                     </del>	<del> </del>	<u> </u>	
Intravascular	<b>-</b>	-	<del> </del>				+		<del>                                     </del>		<del>                                     </del>	
Peripheral Vascular	<del> </del>	<del> </del>	+		<del> </del>		-	+	-	-	<del> </del>	<del> </del>
Laparoscopic	<del> </del>		<del> </del>		<del> </del>		-	-	┼	<del> </del>		
Musculo-skeletal	<del> </del>	· ···	+	<del> </del>	<del> </del>		<del> </del>	<del> </del>	+	╄	<u> </u>	
Superficial												
Musculo-skeletal	┧┈	<u> </u>	1				<del>- </del>	-	1	<del> </del>		
Conventional												
N= new indication	n; 1	P = Pro	eviou	ısly Clear	ed by FI	DA; E=	Added	l unde	r Appe	endix l	E (LTF)	
Additional Comm BDF/PWD; BDF/						:: B/M; B/	PWD;					<del></del>
P	revio	us 510(k	) for t	his device ko	72000							_
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Prescription Use	(Per	21 CI	FR 80	01.109)	īſ	Division Sig	3/1/	m	W	has		
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Radiological Devices 510(k) Number

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		1			T	Mode	of O	perati	on	1		
Clinical Application	В	THI	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative								]				
Neurological												
Pediatric												
Small Organ (Specify)*											,	
Neonatal Cephalic										J		
Adult Cephalic												
Cardiac												
Transesophageal		,										
Transrectal	P	P	P	P	P	P		P				P
Transvaginal	P	P	P	P	P	P		P				P
Transurethral												
Intravascular							ļ					ŀ
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal												
Superficial	<u> </u>					ļ					<u> </u>	
Musculo-skeletal			1								1	
Conventional			<u> </u>	<u> </u>						<u> </u>		<u> </u>
N= new indication  Additional Comm  BDF/PWD; BDF/	ents	:		Combine	d Modes			l unde	r Appo	endix 1	E (LTF)	
	· · · · ·									<del></del>		
	revio	re 510/L	r) for t	his device kí	72000			,			<u>.</u>	

Prescription Use (Per 21 CFR 801.109)

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System Transducer X
Model PLT-1202S
510(k) Number(s)

					<b></b>	Mode	of O	perati	ion			
Clinical Application	В	тні	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic								-			1100	
Fetal						-						
Abdominal				-					·			<del> ·</del>
Intraoperative (Specify)	P	P	P	P	P			Р	i			P
Intraoperative Neurological				1100								<u> </u>
Pediatric		_										
Small Organ (Specify)*	P	P	P	P	P			P	<del>                                     </del>			P
Neonatal Cephalic					1		·			<del>                                     </del>		• • • • • • • • • • • • • • • • • • • •
Adult Cephalic										<del>                                     </del>		
Cardiac									1			· · · · · · · · · · · · · · · · · · ·
Transesophageal								-	1			
Transrectal					<u> </u>		<u> </u>				<del></del>	
Transvaginal												·
Transurethral					· · · · · · · · · · · · · · · · · · ·		<del>                                     </del>					
Intravascular					<u> </u>	-		-	<u> </u>			
Peripheral Vascular	P	P	P	P	P			P				P
Laparoscopic	<u> </u>									ļ		
Musculo-skeletal Superficial	P	P	P	P	P			P			_	P
Musculo-skeletal Conventional	P	P	P	P	P			P				P

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PW	<u>D;</u>
BDF/PWD; BDF/MDF; BD	PF/MDF/PWD	
Previous 510(k	) for this device k072000	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number \_\_\_\_

						Mode	of O	perati	on			
Clinical Application	В	тні	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic										<u> </u>	11077	
Fetal												
Abdominal										<u> </u>		
Intraoperative (Specify)					<u> </u>		<del> </del>			-		
Intraoperative Neurological												
Pediatric									P			
Small Organ (Specify)*							1	-		<del> </del>		
Neonatal Cephalic					<u> </u>					<del> </del>		
Adult Cephalic			1		<u> </u>		<del> </del>					
Cardiac							<del> </del>		P	<u> </u>		
Transesophageal					†			<u> </u>				
Transrectal					<del> </del>			<del></del>		<del> </del>	-	
Transvaginal		_			<b>†</b>	<u> </u>	<del>                                     </del>			1	i	
Transurethral								<del>                                     </del>		<b>†</b>		
Intravascular								<del>                                     </del>	<del>                                     </del>	<b>†</b> -		
Peripheral Vascular							-	<del> </del>	P		-	
Laparoscopic			<b>†</b>		<del>                                     </del>				<del>                                     </del>	<del> </del>		
Musculo-skeletal		Ι					$\vdash$	<del>                                     </del>	<del> </del>	<del>                                     </del>		
Superficial												
Musculo-skeletal											<u> </u>	
Conventional	}		ļ						1			
N= new indication	1; F	P = Pre	eviou	sly Clear	ed by FI	)A; E=.	Added	under	Appe	endix E	E (LTF)	
Additional Comm										- <del></del>		
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Radiological Devices KO8

Division of Reproductive, Abdominal and

(Division Sign-Off)

Prescription Use (Per 21 CFR 801.109)

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	T					Mode	of O	perati	ion			
Clinical Application	В	THI	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic	Combined (Specify)
Ophthalmic	ļ .		<del> </del>								Flow	
Fetai	<u> </u>		1 -									
Abdominal		· · · · · · · · · · · · · · · · · · ·	<del> </del>						<del> </del>			<u>.</u>
Intraoperative (Specify)		_	<b>†</b>		_				<b></b>		!	
Intraoperative Neurological							-		<b></b>			
Pediatric	<b>_</b>						· · · · · · · · · · · · · · · · · · ·	1		_		· · · · · ·
Small Organ (Specify)*								<b> </b>		<del>                                     </del>		
Neonatal Cephalic		<b></b>	1					<b>†</b>				
Adult Cephalic	1	_	<del>                                     </del>		ļ		-	<del> </del>				
Cardiac	ļ		<del>                                     </del>		<del> </del>				<del> </del>	-	·	
Transesophageal	P	P	P	P	<u> </u>	<del></del>	P	P	P			P
Transrectal	1		1					<del>-</del>		ļ		
Transvaginal	1	<u> </u>	-					<del> </del>	-	<del>                                     </del>		
Transurethral	<del> </del>				<u> </u>			<del>                                     </del>	├			
Intravascular	<del> </del>	<u> </u>	<del> </del>				<b> </b>	<u> </u>	-			
Peripheral Vascular	1	1			<del> </del>	· · · · · · · · · · · · · · · · · · ·						
Laparoscopic	† –		<del>                                     </del>					<del>                                     </del>	<u> </u>			
Musculo-skeletal	1		<del></del>					<del> </del>	<del>                                     </del>	\ <u></u>	<del></del>	
Superficial	1	1										
Musculo-skeletal	1	<del>                                     </del>	+		<del> </del>			<del> </del> -	-	<del> </del>		
Conventional							ŀ					
N= new indication	n; I	P = Pr	eviou	isly Clear	ed by FI	OA; E=	Added	unde	r Appe	ndix I	(LTF)	
Additional Comm BDF/PWD; BDF/	ents MD	: F; <u>B</u> D	F/M	Combined DF/PWD:	d Modes ;B-TDI;	: B/M; B/I M-TDI; 2	<u>PWD;</u> D/CW	D; BE	OF/CW	/D;		
	-											
ъ.		£10/l	) fo - 4	Li. d. d l. A	72000							
E1	reviot	12 210(K	j ior t	<u>his device k0</u>	72000	· · · · · · · · · · · · · · · · · · ·				· · · · · ·	····	<del></del>
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		C	oncur	rence of CDF	RH, Office	of Device Eva	luation	(ODE)				

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number \_\_\_\_

System	_ Transducer <u>X</u>	
ModelI	PST-25BT	
510(k) Nur	nber(s)	

						Mode	of O	perati	ion			<del></del>
Clinical Application	В	THI	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic				-					-7			·,
Fetal								-				***
Abdominal	P	P	P	P	P	P	P	P	P			P
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	P	P	P	P	P	P	P	P	P			P
Small Organ (Specify)*												
Neonatal Cephalic	P	P	P	P	P	P	P	P	P			P
Adult Cephalic	P	P	P	P	P	P	P	P	P			P
Cardiac	P	P	P	P	P	P	P	P	P	P		<u>Р</u>
Transesophageal		,	1						<del> </del>			
Transrectal									<del> </del>			
Transvaginal										<b></b>		
Transurethral												
Intravascular												
Peripheral Vascular	1			·								
Laparoscopic					-	7						
Musculo-skeletal			<u> </u>						1			
Superficial	1									}	]	
Musculo-skeletal									1			
Conventional		<u> </u>			l.							

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes	s: B/M; B/PWD;	
BDF/PWD; BDF/MDF;	BDF/MDF/PWD;B-TDI;	M-TDI: 2D/CWD: BDF	F/CWD:
CHI/2D; FEI/2D; CHI/E	BDF; FEI/BDF		<u>· · · · · · · · · · · · · · · · · · · </u>
Previous 5	10(k) for this device k072000		
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

510(k) Number(s)	System Transducer _X Model PLT-604AT	

						Mode	of O	perati	on									
Clinical Application	В	THI	М	Color Doppler	Power	Dynamic Flow	TDI	PW	cw	CHI 2D	CHI Dynamic Flow	Combined (Specify)						
Ophthalmic											1,0%							
Fetal																		
Abdominal																		
Intraoperative (Specify)																		
Intraoperative Neurological																		
Pediatric																		
Small Organ (Specify)*	P	P	P	P	P	P		P				P						
Neonatal Cephalic											· · · · · · ·							
Adult Cephalic									1									
Cardiac					•													
Transesophageal		-																
Transrectal																		
Transvaginal																		
Transurethral																		
Intravascular																		
Peripheral Vascular	P	P	P	P	P	P		P				P						
Laparoscopic																		
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P						
Musculo-skeletal Conventional	P	P	P	P	Р	P		P				P						

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF; BD	F/MDF/PWD	
Previous 510(k	for this device k072000	

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Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

System Transducer _X	
Model PLT-704AT	
510(k) Number(s)	

		Mode of Operation										
Clinical Application	В	ТНІ	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)				,								
Intraoperative Neurological												
Pediatric								T			· · · · · · ·	
Small Organ (Specify)*	P	P	P	P	P	P		P				P
Neonatal Cephalic												*******
Adult Cephalic								· · · · · ·				
Cardiac				,								
Transesophageal												
Transrectal												
Transvaginal									-			
Transurethral										-		
Intravascular												
Peripheral Vascular	P	P	P	P	P	P		P				P
Laparoscopic												
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P
Musculo-skeletal Conventional	P	P	P	P	P	P		P				P

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; I	B/PWD;	
BDF/PWD; BDF/MDF; BD	F/MDF/PWD		
Previous 510(k)	for this device k072000		

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices + 08/065
510(k) Number

System	Transducer X		
Model	PLT-805AT		
510(k) N	lumber(s)	<del></del>	

		Mode of Operation										
Clinical Application	В	THI	M	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	СНІ Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric				******			<u> </u>					
Small Organ (Specify)*	P	P	P	P	P	P		P				P
Neonatal Cephalic								<b></b>				
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal						· · · · · · · · · · · · · · · · · · ·						
Tṛansvaginal												
Transurethral								<u> </u>		1		
Intravascular				···			1	<u> </u>				
Peripheral Vascular	P	P	P	P	P	P		P				P
Laparoscopic						<u> </u>						
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P
Musculo-skeletal Conventional	P	P	P	P	P	P		P				P

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: BDF/PWD; BDF/MDF; BDF/	Combined Modes: B/M; B/PWD; /MDF/PWD	
Previous 510(k) for	or this device k072000	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices 408/065
510(k) Number

System T Model <u>PLT-</u>	<u> 1204</u>		r <u>X</u>									
510(k) Number(	(s) ——											
				· · · · · · · · · · · · · · · · · · ·		Mode	of Oj	perat	ion			<u></u>
Clinical Application	В	ТНІ	М	Color Doppler	Power	Dynamic Flow	IDT	PW	CW	CHI 2D	CHI Dynamic Flow	Combine (Specify
Ophthalmic									<b></b>		Flow	
Fetal	1				_	-	_					<del></del>
Abdominal			1		-							
Intraoperative (Specify)						······································	<b></b>					
Intraoperative Neurological												
Pediatric				-						-		
Small Organ (Specify)*	P	P	P	P	P	P		P				P
Neonatal Cephalic												
Adult Cephalic							-					
Cardiac				<u></u>				-				
Transesophageal										l		<del>- ,</del> .,
Transrectal						<del></del> -	-					
Transvaginal			I						-			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

P

P

P

P

P

P

P

P

P

Additional Comments: _	Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF; B		
Previous 510	(k) for this device k072000	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Transurethral
Intravascular
Peripheral Vascular

Laparoscopic
Musculo-skeletal

Conventional

Superficial Musculo-skeletal

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

						Mode	of O	perat	ion			
Clinical Application	В	ТНІ	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic	1	1				<del></del>	<u> </u>	<del> </del>			Flow	
Fetal	1	<u> </u>	1			<u> </u>	_			-		
Abdominal			<b>†</b>	·		<del></del>				<del>  -</del>		
Intraoperative (Specify)	†	<del> </del>	1						<del>                                     </del>	<del>                                     </del>	<u> </u>	
Intraoperative Neurological			-									
Pediatric												
Small Organ (Specify)*	P	P	P	P	P	Р		P	1		*****	P
Neonatal Cephalic												
Adult Cephalic						<u> </u>				†		
Cardiac												
Transesophageal									<u> </u>			
Transrectal												
Transvaginal	1				1	<u> </u>				<b>!</b>		
Transurethral			<del>                                     </del>			<u> </u>						
Intravascular			1					<del> </del>				
Peripheral Vascular	P	P	P	P	P	P		P	-	İ		P
Laparoscopic							<u> </u>		1			
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P
Musculo-skeletal Conventional N= new indication	P	P	P	P	P	P		P			·	P

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number 408/065

System Transducer <u>X</u> Model <u>PVT-382BT</u>	· .	
510(k) Number(s)		

	ļ		· <del>,</del>			Mode	of O	perati	on			
Clinical Application	В	ТНІ	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	СН1 Dynamic Flow	Combined (Specify)
Ophthalmic					1							
Fetal	P	P	P	P	P	P		P				P
Abdominal	P	P	P	P	P	P		P				P
Intraoperative (Specify)				_								
Intraoperative Neurological		į										"
Pediatric	P	P	P	P	P	P		P				P
Small Organ (Specify)*												
Neonatal Cephalic												<del></del>
Adult Cephalic											-	
Cardiac												
Transesophageal								· · · · · · · · · · · · · · · · · · ·		İ	,.,	
Transrectal									1			
Transvaginal												
Transurethral							*****					
Intravascular										· · · · ·		····
Peripheral Vascular												
Laparoscopic								1			<u> </u>	
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PV	VD;
BDF/PWD; BDF/MDF; E	DF/MDF/PWD	<del></del>
Previous 510	O(k) for this device k072000	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number .

		,				Mode	of Op	perat	ion		<del></del>	
Clinical Application	В	THI	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combine (Specify
Ophthalmic	ļ				-		-		_	<del> </del>	FIOW	
Fetal	P	P	P	P	P	P		P		-		P
Abdominal	P	P	P	P	P	Р	-	P	<u> </u>	-		P
Intraoperative (Specify)	<u> </u>		· · - ·							<del>                                     </del>		
Intraoperative	1							<u> </u>	-	-		<u> </u>
Neurological	L											
Pediatric												
Small Organ (Specify)*										<del> </del>		
Neonatal Cephalic										<del> </del>		
Adult Cephalic	Ī						1			1		
Cardiac												
Transesophageal								<u> </u>				<del></del>
Transrectal							<b>.</b>		<del>                                     </del>	<del> </del>		
Transvaginal							-			ľ	<u> </u>	
Transurethral										†		
Intravascular												
Peripheral Vascular										ļ	<del>                                     </del>	
Laparoscopic				-	<del> </del>				† ·			
Musculo-skeletal					1				ļ <u>-</u>	ļ — —		<del> </del> -
Superficial	ļ											
Musculo-skeletal				-								
Conventional	<u> </u>	ļ					1.					
N= new indication  Additional Comm  BDF/PWD; BDF/	ents	<b>:</b>		Combined		OA; E = / : B/M; B/I		under	Appe	endix E	E (LTF)	
***												
n		o £10/!-	. <b></b>	hin dania 10	<b>73000</b>	·					· · · · · · · · · · · · · · · · · · ·	
P	eviou	s 510(k	for t	his device k0	72000							

Prescription Use (Per 21 CFR 801.109)

						Mode	of O	perati	ion			
Clinical Application	В	тні	·M	Calor Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic		<u> </u>									Flow	
Fetal	P	P	P	P	P	P	<del> </del>	P				Р.
Abdominal		<del> </del>	1						<del></del>	<del> </del> -	· <del></del> -	
Intraoperative (Specify)			1					<del>                                     </del>			· · · · · · · · · · · · · · · · · · ·	
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)*	1								-			
Neonatal Cephalic		1	1									
Adult Cephalic	<u> </u>											
Cardiac				-						<del>  -</del> -		
Transesophageal		ŀ	1 "				1					
Transrectal			<u> </u>					1				
Transvaginal								<del> </del>		<u> </u>		
Transurethral										<u> </u>		
Intravascular										1		
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal										<u> </u>		
Superficial		<u></u>		·				<u> </u>				
Musculo-skeletal												
Conventional								unde				

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

oior Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamie Flow	Combined (Specify)
			-		ļ		
P P	P		P				P
		İ				1	
			under	Appe	ndix E	E (LTF)	
							_
vice k072000							
	Cleared by FD	Cleared by FDA; E = Abined Modes: B/M; B/M	Cleared by FDA; E = Added	Cleared by FDA; E = Added under	Cleared by FDA; E = Added under Appe	Cleared by FDA; E = Added under Appendix E	Cleared by FDA; E = Added under Appendix E (LTF)  Abined Modes: B/M; B/PWD;

Prescription Use (Per 21 CFR 801.109)

System Transducer X	
Model PST-30BT	
510(k) Number(s)	

		·	- <del></del>			Mode	of O	perati	ion			
Clinical Application	В	ТНІ	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic								,			1.011	
Fetal							1					
Abdominal	P	P	P	P	P	P	P	P	P			P
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	P	P	P	P	P	P	P	P	P			P
Small Organ (Specify)*		_			-							
Neonatal Cephalic	P	P	P	P	P	P	P	P	P			P
Adult Cephalic	P	P	P	P	P	P	P	P	P			P
Cardiac	P	P	P	P	P	P	P	P	P	P		P
Transesophageal				······································					_	<u> </u>		
Transrectal												
Transvaginal					****							·
Transurethral	1				1				1			
Intravascular			1						<u> </u>			,
Peripheral Vascular									<del> </del>			
Laparoscopic								<u> </u>	<u> </u>		<del>                                     </del>	
Musculo-skeletal Superficial												
Musculo-skeletal Conventional											_	

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;
	DF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;
CHI/2D; FEI/2D; CHI/BD	DF, FEI/BDF
<u> </u>	
Previous 510(	k) for this device k072000

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

linical Application	В	Mode of Operation										
	ь	THI	М	Color Doppler	Power	Dynamic Flow	TDI	PW	cw	CHI 2D	CHI Dynamic Flow	Combine (Specify
)phthalmic				1900							11011	
etal												
bdominal												<del></del> -
ntraoperative (Specify)					1					-		
ntraoperative Jeurological		•										
ediatric	P	P	P	P		<del></del>	P	P	P			P
mall Organ (Specify)*				***************************************								
eonatal Cephalic	P	P	P	P			P	P	P			P
dult Cephalic							<del> </del>					
	P	P	P	P	<del> </del>	i ·	P	P	P			P
ransesophageal								<u> </u>				
ransrectal					1							
ransvaginal												
ransurethral												
ntravascular					Ï		1	·				••
eripheral Vascular						-						
aparoscopic											-	
fusculo-skeletal uperficial												
lusculo-skeletal									<u> </u>			
onventional  N= new indication;						<u> </u>						

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Clinical Application	510(k) Number(s							. ,				<del></del>	
Ophthalmic Fetal Abdominal Intraoperative (Specify) Intraoperative Neurological Pediatric P P P P P P P P P P P P P P P P P P P							Mode	of O	perat	ion			
Ophthalmic         Fetal           Abdominal         Intraoperative (Specify)           Intraoperative (Specify)         Intraoperative           Neurological         P P P P P P P P P P P P P P P P P P P	Clinical Application	В	THI	М		Power		TDI	PW	CW	1	Dynamic	
Abdominal	Ophthalmic												
Intraoperative (Specify)	Fetal												
Intraoperative Neurological Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Pediatric Peripheral Pediatric Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)  Additional Comments:  Combined Modes: B/M; B/PWD;	Abdominal												
Neurological	Intraoperative (Specify)												
Neonatal Cephalic  Neonatal Cephalic  Cardiac  P P P P P P P P P P P P P P P P P P													
Neonatal Cephalic	Pediatric	P	P	P	P			P	P	P			P
Adult Cephalic Cardiac PPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPP	Small Organ (Specify)*	1											
Cardiac P P P P P P P P P P P P P P P P P P P	Neonatal Cephalic	P	P	P	P			P	P	P			P
Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)  Additional Comments: Combined Modes: B/M; B/PWD;	Adult Cephalic					1							
Transvaginal Transvaginal Transvaginal Transvaginal Transvaginal Transvaginal  Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)  Additional Comments:  Combined Modes: B/M; B/PWD;	Cardiac	P	P	P	P			P	P	P		1	P
Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)  Additional Comments:  Combined Modes: B/M; B/PWD;	Transesophageal												
Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)  Additional Comments:  Combined Modes: B/M; B/PWD;	Transrectal		1										
Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments:  Combined Modes: B/M; B/PWD;	Transvaginal												
Peripheral Vascular  Laparoscopic  Musculo-skeletal Superficial  Musculo-skeletal Conventional  N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)  Additional Comments: Combined Modes: B/M; B/PWD;	Transurethral												
Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)  Additional Comments: Combined Modes: B/M; B/PWD;	Intravascular												
Musculo-skeletal Superficial  Musculo-skeletal Conventional  N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)  Additional Comments: Combined Modes: B/M; B/PWD;	Peripheral Vascular										1		
Superficial  Musculo-skeletal Conventional  N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)  Additional Comments: Combined Modes: B/M; B/PWD;	Laparoscopic												
N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)  Additional Comments: Combined Modes: B/M; B/PWD;													
N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)  Additional Comments: Combined Modes: B/M; B/PWD;	Musculo-skeletal												
Additional Comments: Combined Modes: B/M; B/PWD;	The state of the s			į									
					·-	•	-		l unde	r App	endix ]	E (LTF)	
<u>DDF/FWD; BDF/MDF; BDF/MDF/FWD;B-1DI; M-1DI; 2D/CWD; BDF/CWD;</u>						-			ים, די	NE/CV	ιπ.		
CHI/2D; FEI/2D; CHI/BDF; FEI/BDF						<u>;B-TDI;</u>	M-1DI; 2	D/CW	D; BI	DF/CV	<u>VD;</u>		
	-					······	······································						

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Prescription Use (Per 21 CFR 801.109)

Previous 510(k) for this device k072000

						Mode	of O	perati	on			
Clinical Application	В	THI	М	Calor Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic	1.		1								1104	<u> </u>
Fetal												
Abdominal												
Intraoperative (Specify)	†						<del>                                     </del>					
Intraoperative Neurological												-
Pediatric												
Small Organ (Specify)*	P	P.	P	P	P	P		P				P
Neonatal Cephalic											•	
Adult Cephalic												
Cardiac												
Transesophageal				-								
Transrectal												
Transvaginal												
Transurethral												
Intravascular		Ī -									,	
Peripheral Vascular	P	P	P	P	P	P		P				P
Laparoscopic												
Musculo-skeletal Superficial	P	P	P	P	P	P		P				P
Musculo-skeletal Conventional	P	P	P	P	P	P		P				P

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

SystemT Model <u>PLT-1</u> 510(k) Number(	204		r <u>X</u>											
	Mode of Operation													
Clinical Application	В	ТНІ	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)		
Ophthalmic										<del> </del>	TIOW	·		
Fetal	-											-		
Abdominal														
Intraoperative (Specify)					· · · · · ·				<del></del>					
Intraoperative Neurological														

P

P

P

P

P

P

P

P

P

P

P Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

P

P

P

Additional Comments:	Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF; BD		
Previous 510(k	) for this device k072000	
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Prescription Use (Per 21 CFR 801.109)

P

P

P

Pediatric

Small Organ (Specify)\*

Neonatal Cephalic Adult Cephalic Cardiac

Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular

Laparoscopic Musculo-skeletal

Superficial Musculo-skeletal

> (Division Sign-Off) Division of Reproductive, Abdominal and Radiological Devices 510(k) Number \_\_\_

	<u> </u>			•		Mode	of O	20124	lan	<del></del>	·····	
Clinical Application	В	тні	М	Color Doppler	Power	Dynamic Flow	TDI	PW	cw	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic											7.5	
Fetal	P	P	P	P	P	P		P				P
Abdominal	Р	P	P	P	P	Р		P				· P
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	P	P	P	Р	P	P		P				P
Small Organ (Specify)*		<u> </u>						<del> </del>	<del> </del>	<del> </del>		
Neonatal Cephalic					1				ļ	<b></b>		
Adult Cephalic	<u> </u>			· · · · · · · · · · · · · · · · · · ·				1				
Cardiac									ļ			
Transesophageal										·		1
Transrectal				······································								
Transvaginal		1					-				_	
Transurethral												
Intravascular									1			
Peripheral Vascular					1					1		
Laparoscopic						-		1				
Musculo-skeletal												
Superficial	1					1				ł		
Musculo-skeletal							1				1	
Conventional							1			ŀ	Ĭ	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Previous 510(k) for this device k072000

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

					<del></del>	Mode	of O	narati	lon		<del></del>	
Clinical Application	В	ТНІ	М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic											1100	
Fetal												
Abdominal					-				<del> </del> -	<del> </del>		
Intraoperative (Specify)								<u> </u>				
Intraoperative Neurological												
Pediatric					1							
Small Organ (Specify)*					<del>                                     </del>				<u> </u>	-		
Neonatal Cephalic		·							<u> </u>			
Adult Cephalic												
Cardiac										<u> </u>		
Transesophageal							1					
Transrectal	P	P	P	P	P	P		P				P
Transvaginal	P	P	P	P	P	P		P			<u> </u>	P
Transurethral	1				<u> </u>			<u> </u>	<del>                                     </del>			<del></del>
Intravascular							·····	1				
Peripheral Vascular							-	<del>                                     </del>	<u> </u>			
Laparoscopic		ļ		-	1	-		·····	<del></del>	1		
Musculo-skeletal Superficial												
Musculo-skeletal					1	-				<u> </u>	-	
Conventional							1					

Previous 510(k) for this device k072000

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number \_\_\_\_

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	Mode of Operation											
Clinical Application	В	THI	M.	Color Doppler	Power	Dynamic Flow	TDI	PW	cw	CHI 2D	CHI Dynamic	Combined (Specify)
Ophthalmic		<b></b>					<del> </del> -		<del>                                     </del>		Flow	
Fetal					<del>                                     </del>	<u> </u>		<del> </del> -				
Abdominal	İ				_				-			<del></del>
Intraoperative (Specify)	-	-			<del>                                     </del>			<del>                                     </del>				
Intraoperative Neurological												·
Pediatric										1		
Small Organ (Specify)*												
Neonatal Cephalic								_				_
Adult Cephalic	L											
Cardiac												
Transesophageal	P	P	P	P			P	P	P			P
Transrectal											<del>                                    </del>	
Transvaginal										****		
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal												
Superficial	<u> </u>											
Musculo-skeletal												
Conventional	<u> </u>	<u> </u>										
N= new indication	ı; P	P = Pre	viou	sly Cleare	ed by FD	A; E = A	Added	under	Appe	ndix E	(LTF)	
				•					••		` ,	•
Additional Comm	ents	:	- 1	Combined	d Modes	: B/M; B/F	WD;					
BDF/PWD; BDF/	MD)	F; <u>BD</u>	<u>F/M</u> ]	<u>DF/PWD;</u>	<u>B-TDI; </u>	<u>M-TDI; 21</u>	D/CW	D; <u>BD</u>	F/CW	<u>D;</u>		
-		F102:										
Pr	eviou	s 510(k)	<u>) for ti</u>	iis device k0	72000							

A-27

(Division Sign-Off)

510(k) Number \_\_\_\_

Division of Reproductive, Abdominal and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

Clinical Application  Ophthalmic  Fetal  Abdominal	В	THI	Т	Mode of Operation											
Fetal			М	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)			
			1							<del> </del>	110W				
Abdominal												· · · · · · · · · · · · · · · · · ·			
				· —					<del>                                     </del>			_			
Intraoperative (Specify)		<b></b>		<del> </del>		_	<del> </del>		<u> </u>	<del> </del>					
Intraoperative			1 - 1				<del> </del>		<u> </u>						
Neurological				,											
Pediatric					<del> </del>		<del> </del>		N		-				
Small Organ (Specify)*						<u> </u>	<u> </u>					<del> </del>			
Neonatal Cephalic					<del> </del>		1		1	-	<del></del> -	<u> </u>			
Adult Cephalic			<del> </del>				1		<del>                                     </del>	<del> </del>					
Cardiac					ļ · · · · ·		-		N	-					
Transesophageal			1		<del> </del>		<del>                                     </del>		IX						
Transrectal					<u> </u>		<del>                                     </del>		<u> </u>						
		-	-		<del> </del>		-		-						
Transvaginal			-				<del> </del>			<u> </u>	,				
Transurethral			-		ļ		ļ		—	<del> </del>					
Intravascular	ļ		_		-		<u> </u>		ļ		ļ	ļ			
Peripheral Vascular								<u> </u>	N						
Laparoscopic	ļ	ļ	↓				ļ				ļ				
Musculo-skeletai		ļ			İ		1								
Superficial		<u> </u>	1						ļ <u> </u>	ļ					
Musculo-skeletal				ļ						1					
Conventional N= new indication		Ĺ					<u> </u>								
Additional Commo	ents	:									1.0				
	(					CONTINUE ON CO			EDED)						
Prescription Use (	Per	21 CI	FR 80	01.109)		(Div	rision	Ary Sign-0	1 <u>/</u> ft)	hi	why	<del></del>			